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Atty. Docket No.: 99-256

711/IDS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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MAY 24 2001

TECHNOLOGY CENTER R3700



In re Application of:)
THOMPSON et al.)
Serial No.: 09/365,278)
Filed: July 30, 1999)
Title: PROGRAMMABLE INJECTOR)
CONTROL)

) Art Unit: 3737

) Examiner: Jeoyuh Lin

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner
for Patents
Washington, D.C. 20231

Dear Sir:

This Information Disclosure Statement is being filed in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98. The items listed on the attached Forms PTO-1449 may be deemed to be relevant to the patentability of the above-identified application, and are made of record to assist the Patent and Trademark Office in its examination of this application. Nevertheless, Applicants do not acknowledge or admit that the listed items are or constitute prior art under the relevant patent laws, and reserve the right to contest the prior art status of any of the listed items.

I. OPTISTAR™ MR Digital Injection System and MR SONIC SHOT 50 Injector

On information and belief, Liebel-Flarsheim Company, a Mallinckrodt company, submitted a 510(k) application to the FDA on November 4, 1998, to obtain approval to market the OPTISTAR MR Injector System in the United States. The FDA approved the

510(k) application for the OPTISTAR MR Injector System in December of 1999.

Subsequent to FDA approval, Mallinckrodt and Leibel-Flarsheim began selling the OPTISTAR MR Injector System in the United States.

On information and belief, Mallinckrodt provides the OPTISTAR™ MR Digital Injection System Operator's Manual, including pages 1-3, 1-7, 3-1 to 3-17 and 4-2 to 4-9 thereof, which is dated November of 1999, to purchasers of the OPTISTAR MR Injector System.

Even though the OPTISTAR manual is dated (and the OPTISTAR MR injector was sold in the United States) subsequent to the filing date of this application, on information and belief Applicants submit that the OPTISTAR MR injector may be substantially similar to an MR injector – the Sonic Shot 50 – developed and sold in Japan by Nemoto Kyorindo Co., Ltd. (“Nemoto”) of Osaka, Japan, prior to the filing date of this application. Applicants submit herewith a copy of a Japanese-language Sonic Shot 50 Operator's Manual (Version 2.0.0) dated December 24, 1999, which Applicants assume was distributed by Nemoto to Japanese purchasers of the Sonic Shot 50 injector. (An English translation of Chapter 11 of the Sonic Shot 50 Manual is submitted herewith.) Earlier versions of the Sonic Shot 50 Manual may exist and may have been distributed by Nemoto to Japanese purchasers of its Sonic Shot 50 injector, but Applicants have not been able to locate any to date.

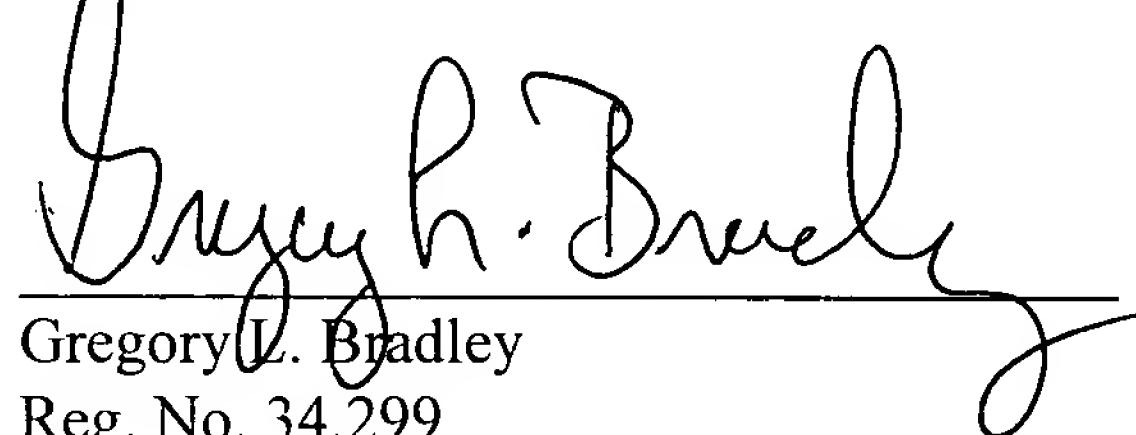
II. Submission Fee for IDS

This Information Disclosure Statement is being filed after the mailing date of a first office action on the merits, but before the mailing date of a final action or a notice of

allowance. Consequently, this Information Disclosure Statement is accompanied by the fee set forth in 37 C.F.R. §1.17(p).

The Examiner is respectfully requested to initial copies of the attached Forms PTO-1449 to show consideration of the references, and to return the initialed forms to the undersigned counsel.

Respectfully submitted,

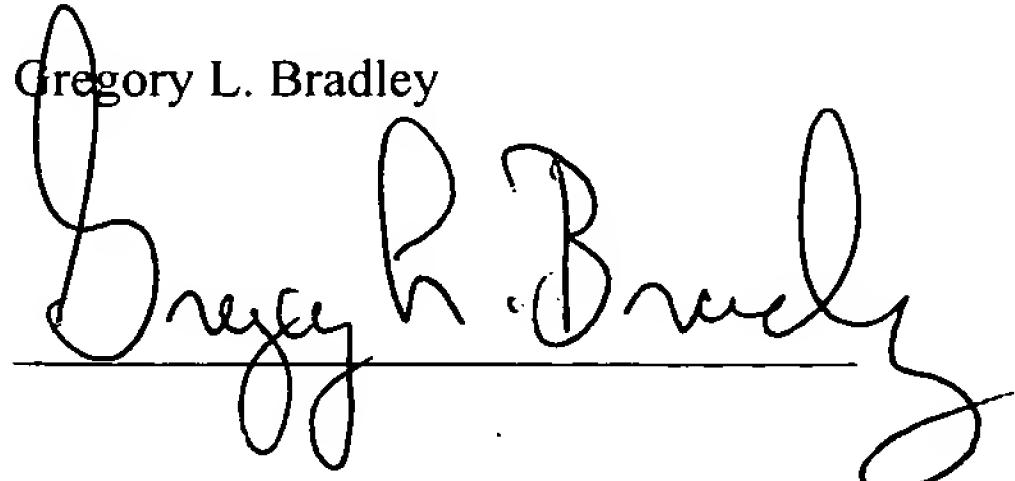


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CERTIFICATE OF MAILING

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on May 17, 2001, with sufficient postage as first-class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Gregory L. Bradley


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